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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,863	12/31/2001	Bruce Robie	Implex-13	4928

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DUANE MORRIS LLP
100 COLLEGE ROAD WEST, SUITE 100
PRINCETON, NJ 08540-6604

EXAMINER

PHILOGENE, PEDRO

ART UNIT PAPER NUMBER

3732

DATE MAILED: 01/30/2004

1)

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,863

Applicant(s)

ROBIE ET AL.

Examiner

Pedro Philogene

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-- Th MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15-17 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 16, 21-23 and 25-34 is/are rejected.
- 7) ☒ Claim(s) 17 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims, 1,15,16,23,25,29 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilhelmy (5,722,977).

With respect to claim 1, Wilhelmy discloses an instrument system (8) for preparing a disc space between adjacent vertebral bodies to receive a repair device, the instrument system comprising: at least one distractor (15) including a tapered body section (17) for distracting the vertebral bodies in a manner that restores natural lordosis of the lumbar and cervical spines; as set forth in column 5, lines 44-67; column 6, lines 1-67; the tapered body section formed by an end wall (22) a first pair of opposing walls portions (19,21) converging toward the end wall (22); and a second pair of opposing wall portions 19',21') converging toward the end wall, as set forth in column5, lines 44-67.

With respect to claim 15, Wilhelmy discloses a distractor (8) for use in a system that prepares a disc space between adjacent vertebral bodies to receive a repair device, the distractor (15) comprising a tapered body section (17) for distracting the vertebral bodies in a manner that restores natural lordosis of the lumbar and cervical spines; as set forth in column 5, lines 44-67; column 6, lines 1-67; ; the tapered body section formed by an end wall (22) a first pair of opposing walls portions (19,21) converging

toward the end wall (22); and a second pair of opposing wall portions 19',21')
converging toward the end wall, as set forth in column5, lines 44-67.

With respect to claims 16,23,25,29, Wilhelmy discloses all the limitations, as set forth, for example a connector section (16) for coupling a handle to the distractor, and a female coupling element (28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21,22, 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilhelmy (5,722,977) in view of Burkus et al (6,648,895).

With respect to claims 21,22,26-34, it is noted that Wilhelmy teaches all the limitations, except for a female coupling member formed by a T-Shape slot defining inwardly facing locking flanges; as claimed by applicant. However, in a similar art, Burkus et al evidences the use of a female coupling member formed by a T-shape slot defining inwardly facing locking flange configured to receive the flange posts of the distractor and drive the distractor into the disc space.

Therefore, given the teaching of Burkus et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the female coupling member of the device of Wilhelmy, as taught by Burkus et al to provide a

device with a T-shape slot defining inwardly facing locking flange configured to receive the flange posts of the distractor and drive the distractor into the disc space.

As to the grooves on the pair of wall portions, as claimed by applicant; Burkus et al evidence that such a groove would have been obvious to engage the vertebral endplates and resist movement of distractor tip in the disc space.

Therefore, given the teaching of Burkus et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pair of wall portions of Wilhelmy, as taught by Burkus et al to provide a surface to engage the vertebral endplates and resist movement of the distractor tip in the disc space.

Allowable Subject Matter

Claims 17,24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

Applicant's arguments filed 11/28/03 have been fully considered but they are not persuasive. Applicant stated in the remark that the spacer of whihelmy only has one pair of opposing wall portions 19' and 21' which converge toward the end wall 22. This statement is in error; and, applicant's attention is directed to '977 column 5, lines 44-67, where applicant would find top and bottom surfaces 19, 21 and 19' and 21' converging toward the end wall.

Furthermore, in paper #7, which, by the way, was an Election of Species, applicant elected claims 1,15-17 for prosecution without traverse. In addition, since

there was not any generic claim, all the other non-elected claims were cancelled.

However, applicant stated in the remark that "since claim 1 is believed to be allowable and generic to dependent claims 2-14, it is respectfully submitted that claims 2-14 should now be considered on the merits as provided by 37 CFR 1.141."

Even if claim 1, was not under final rejection, claims 2-14 would not be rejoined with claim 1, since there was not a generic claim in the election of species.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

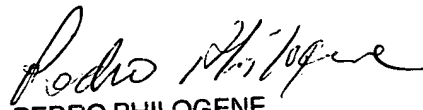
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703)

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308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


PEDRO PHILOGENE
PRIMARY EXAMINER

Pedro Philogene
January 28, 2004